Supporting Statement for Paperwork Reduction Act Submission:
Approval Procedures for Nontoxic Shot and Shot Coatings
OMB control number 1018-0067
50 CFR 20.134

Section A. Justification

1. Explain why you need to collect this information. Identify any legal or administrative requirements that necessitate this information collection.

As of January 1,1991, lead shot was banned for hunting waterfowl and coots in the United States. At that time, steel shot was the only nontoxic alternative available. Since then, the U.S. Fish and Wildlife Service (Service or "we") has encouraged manufacturers to develop other alternatives that the hunting public may use. In approving a candidate material as nontoxic for hunting waterfowl and coots, we must first ensure that secondary exposure (ingestion of spent shot or its components) are not a hazard to migratory birds and the environment. In order to make this decision, we require the applicant to collect information about the toxicity of their candidate material to migratory birds and the environment. A further requirement pertains to law enforcement. A noninvasive field detection device must be available to distinguish the candidate shot from lead shot. The above information provides the bulk of an application for approval of nontoxic shot. Once a candidate material is approved as nontoxic, there is no seasonal or annual information collection requirement.

Under the Migratory Bird Treaty Act, “the duties and powers of the Department of Interior include the preservation, distribution, introduction, and restoration of game birds and other wild birds. The Secretary of the Interior shall from time to time collect and publish useful information as to the propagation, uses, and preservation of such birds. And the Secretary of the Interior shall make and publish all needful rules and regulations for carrying out the purposes of this Act, and shall expend for said purposes such sums as the Congress may appropriate thereafter” (16 U.S.C. 701, 703, & 704).

The Fish and Wildlife Act of 1956 (16 U.S.C. 742a-742j, not including 742 d-l), as amended, among other things, directs a program of continuing research, extension, and information services on fish and wildlife matters, both domestically and internationally.

2. Explain how FWS will use the information. If this is not a new collection, explain how FWS has used the information received.

The information from the scientific literature, risk assessment analysis, and toxicity studies will be gathered and packaged by the applicant (company producing and/or marketing the shot or shot coating). We will use that information about the candidate material to approve or deny a designation as nontoxic for hunting waterfowl and coots. In 1992, the first application was received. The experience of this application led to the revision of the test protocol to employ an ecosystem approach, as well as to reduce the time, expense, and burden on the Federal government and the applicant. For the past few years, the revised test protocol has worked well for us and for our applicants.

3. Does this information collection use automated, electronic, mechanical, or other technological techniques? Provide the reasons for the decision to adopt this means of collection. Describe any consideration you gave to using information technology to reduce burden on the public.

The revised protocol allows the submission of automated or electronic risk assessment analysis and modeling. The basis for adopting this decision was to take advantage of new advances in science and technology, to reduce the expense and time burden for the applicant and the federal government, and to limit the use of live animals in toxicity testing. In some cases, this will allow the applicant to submit a wholly electronic application. In addition, further animal testing may be unnecessary, and the applicant can rely on information already available.

4. Describe efforts to identify duplication. Show why similar information already available cannot be used or modified.

By incorporating the use of information previously collected, background information, risk assessments, and toxicity tests need not be duplicated. Therefore, we have reduced the duplication of effort that was inherent in the previous protocol. Information already available on toxicity of the candidate material will be incorporated into the application.

5. If the collection will have a significant impact on small entities, such as small businesses, describe methods used to minimize burden on them.

The information being required does not specifically impact small businesses or other small entities. Our applications to date have come from large manufacturing firms that stand to gain monetarily when their candidate material comes into the marketplace.

6. Describe the consequences to Federal programs or policies if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Information is only collected on a specific candidate material from the applicant (manufacturer) during the application process. If the information is not provided, we cannot make a ruling on whether the candidate material is nontoxic to waterfowl and the environment. If no determination can be made about a candidate material's toxicity, use of the candidate material (shot) would remain illegal. Furthermore, if a field detection device is not available, the candidate shot would remain illegal. This would limit the new types of nontoxic shot available to the hunting community. Information is not collected on a continuing basis.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

There are no special circumstances that would require this collection to be conducted in a manner inconsistent with OMB guidelines.

8. Cite and provide a copy of the 60-day Federal Register notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received on the 60-day notice, and describe actions taken by FWS in response to those comments. Specifically address comments received on cost and hour burden. Describe your efforts to consult with persons outside of FWS to obtain their views on the availability of data; frequency of collection; clarity of instructions, disclosure, or reporting format; and data elements to be recorded, disclosed, or reported. Consultation should include obtaining their views on the amount of burden to be imposed and ways to minimize the burden. If circumstances prevent this consultation, describe them.

On March 24, 2003, we published in the **Federal Register** (68 FR 14257) a notice soliciting public comment on this information collection for 60 days, ending May 23, 2003. We did not receive any comments.

In addition, consultations with the Biological Resources Division (USGS), manufacturers, environmental groups, and university and private sector toxicologists led to the revision of the nontoxic shot protocol.

Consultation with the applicant will occur at regular intervals during the application process.

9. Explain any decision to provide a gift or payment to respondents, other than remuneration of contractors and grantees.

There are no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or policy.

Once an application is presented to us, it becomes public domain, and a summary of the application is subsequently published in the **Federal Register** as a Notice of Application. Material submitted by an applicant as part of the application is subject to the Freedom of Information Act.

11. Provide justification for any questions of a sensitive nature. Include the reasons why the questions are necessary, the specific uses for the information, the explanation given to respondents, and steps taken to obtain respondents' consent.

We do not ask any questions of a sensitive nature.

12. Provide estimates of the hour burden of the information collection. Include an estimate of the dollar value of the burden hours.

The information collection in the nontoxic shot protocol is for a specific candidate

material from an applicant that intends to market the material to the sport hunting community.

In the last four years, we have received five applications. The hour burden of the collection of information varies with each applicant and depends heavily on the relative information already available. We estimate that the hour burden can range from 80 to 6,400 hours and will average 3,200 hours per applicant. The hour burden is considered part of product development to the manufacturer. We estimate no more than one applicant per year. At $20.00 per hour, the total dollar value of the annual burden hours would amount to $64,000.

Annual Applicants	Average Time Required Per Response	Total Annual Burden Hours	Dollar Value of Total Annual Burden Hours (@ $20.00 per hour)
1	3,200 hours	3,200 hours	$64,000

We require no specific forms to be completed by the applicant, but we provide comprehensive guidelines for the components of a complete application (see 50 CFR 20.134).

13. Provide an estimate for the total annual non-hour dollar cost burden to respondents or recordkeepers. Do not include the cost of burden hours described in items 12 and 14.

There is no annual non-hour dollar cost burden to applicants; there is no fee to apply for approval of a new shot material as nontoxic.

14. Provide estimates of the annual cost to the Federal Government. Include a description of the method used to estimate cost, which should include quantification of hours, operational expenses, and any other expense that would not have been incurred without this collection of information.

The total cost to the Federal government to review an application, consult with other divisions within the Service, consult with other agency or university toxicologists, consult with the applicant, and prepare and publish necessary notices in the **Federal Register** is approximately $75,000. This amount will vary, however, depending on the comprehensiveness of the initial application. It is important to remember that the application process occurs only once for a shot material; after that, no other information collections are necessary.

15. Provide the reasons for any program changes or adjustments reported in items 13 or 14 of OMB 83-I.

There are no program changes or adjustments reported in items 13 or 14 of OMB 83-I.

We are requesting the same number of hours that we currently have approved.

16. For collections whose results will be published, outline the plans for tabulation and publication.

The information collected will be published in the **Federal Register** as a basis for our decision whether to grant or deny approval as a nontoxic shot or shot coating for sport hunting.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable. We will display the expiration date for OMB approval.

18. Explain each exception to the certification statement identified in item 19 of OMB 83-I.

Not applicable. There are no exceptions to the certification statement.

Section B. Collections of Information Employing Statistical Methods

Statistical methods are not employed.